SECTION 2

Note: Figures and Tables are not available in the Internet version.

MONITORING STRATEGY

The objective of this section is to describe the strategy recommended by the EPA Office of Water for use by States in their fish and shellfish contaminant monitoring programs. A two-tiered strategy is recommended as the most cost-effective approach for State contaminant monitoring programs to obtain data necessary to evaluate the need to issue fish or shellfish consumption advisories. This monitoring strategy is shown schematically in Figure 2-1 and consists of

- **Tier 1—Screening studies** of a large number of sites for chemical contamination where sport, subsistence, and/or commercial fishing is conducted. This screening will help States identify those sites where concentrations of chemical contaminants in edible portions of commonly consumed fish and shellfish indicate the potential for significant health risks to human consumers.

- **Tier 2—Two-phase intensive studies** of problem areas identified in screening studies to determine the magnitude of contamination in edible portions of commonly consumed fish and shellfish species (**Phase I**), to determine size-specific levels of contamination, and to assess the geographic extent of the contamination (**Phase II**).

This basic approach of using relatively low-cost, nonintensive screening studies to identify areas for more intensive followup sampling is used in a variety of water quality programs involving public health protection (California Environmental Protection Agency, 1991; Oregon Department of Environmental Quality, 1990; TVA, 1991; U.S. EPA, 1989d).

One key objective in the recommendation of this approach is to improve the data used by States for issuing fish and shellfish consumption advisories. Other specific aims of the recommended strategy are

- To ensure that resources for fish contaminant monitoring programs are allocated in the most cost-effective way. By limiting the number of sites targeted for intensive studies, as well as the number of target analytes at each intensive sampling site, screening studies help to reduce overall program costs while still allowing public health protection objectives to be met.

- To ensure that sampling data are appropriate for developing risk-based consumption advisories.

- To ensure that sampling data are appropriate for determining contaminant concentrations in various size (age) classes of each target species so that States can give size-specific advice on contaminant concentrations (as appropriate).

- To ensure that sampling designs are appropriate to allow statistical hypothesis testing. Such sampling designs permit the use of statistical tests to detect a difference between the average tissue contaminant concentration at a site and the human health screening value for any analyte.

The following elements must be considered when planning either screening studies or more intensive followup sampling studies:

- Study objective
- Target species (and size classes)
- Target analytes
- Target analyte screening values
- Sampling locations
- Sampling times
- Sample type
- Sample replicates
- Sample analysis
- Data analysis and reporting.

Detailed guidance for each of these elements, for screening studies (**Tier 1**) and for both Phase I and Phase II of intensive studies (**Tier 2**), is provided in this document. The key elements of the monitoring strategy are summarized in Table 2-1, with reference to the section number of this document where each element is discussed.

2.1 SCREENING STUDIES (TIER 1)

The primary aim of screening studies is to identify frequently fished sites where concentrations of chemical contaminants in edible fish and shellfish composite samples exceed specified human health screening values and thus require more intensive followup sampling. Ideally, screening studies should include all waterbodies where commercial, recreational, or subsistence fishing is practiced; specific sampling sites should include areas where various types of fishing are conducted routinely (e.g., from a pier, from shore, or from private and commercial boats), thereby exposing a significant number of individuals to potentially adverse health effects. Composites of skin-on fillets (except for catfish and other scaleless species, which are usually prepared as skin-off fillets) and edible portions of shellfish are recommended for contaminant analyses in screening studies to provide conservative estimates of typical exposures for the general population. **Note:** If consumers remove the skin and fatty areas from a fish before preparing it for eating, exposures to some contaminants can be reduced (Armbruster et al., 1987, 1989; Cichy, Zabik, and Weaver, 1979; Foran, Cox, and Croxton, 1989; Gall and Voiland, 1990; Reinert, Stewart, and Seagram, 1972; Sanders and Haynes, 1988; Skea et al.,

1979; Smith, Funk, and Zabik, 1973; Voiland et al., 1991; Wanderstock et al., 1971; Zabik, Hoojjat, and Weaver, 1979).

Because the sampling sites in screening studies are focused primarily on the most likely problem areas and the numbers of commonly consumed target species and samples collected are limited, relatively little detailed information is obtained on the magnitude and geographic extent of contamination in a wide variety of harvestable fish and shellfish species of concern to consumers. More information is obtained through additional intensive followup studies (**Tier 2, Phases I and II**) conducted at potentially contaminated sites identified in screening studies.

Although the EPA Office of Water recommends that screening study results not be used as the sole basis for conducting a risk assessment, the Agency recognizes that this practice may be unavoidable if monitoring resources are limited or if the State must issue an advisory based on detection of elevated concentrations in one composite sample. States have several options for collecting samples during the **Tier 1** screening study (see Figure 2-1), which can provide additional information on contamination without necessitating additional field monitoring expenditures as part of the **Tier 2** intensive studies.

The following assumptions are made in this guidance document for sampling fish and shellfish and for calculating human health SVs:

- Use of commonly consumed target species that are dominant in the catch and have high bioaccumulation potential

- Use of fish fillets (with skin on and belly flap tissue included) for scaled finfish species, use of skinless fillets for scaleless finfish species, and use of edible portions of shellfish

- Use of fish and shellfish above legal size to maximum size in the target species

- Use of a 10^{-5} risk level, a human body weight of 70 kg (average adult), a consumption rate of 6.5 g/d for the general population, and a 70-yr lifetime exposure period to calculate SVs for carcinogens. **Note:** The EPA is currently reviewing the 6.5-g/d consumption rate for the general population.

- Use of a human body weight of 70 kg (average adult) and a consumption rate of 6.5 g/d for the general population to calculate SVs for noncarcinogens.

- Use of no contaminant loss during preparation and cooking or from incomplete absorption in the intestines.

For certain site-specific situations, States may wish to use one or more of the following exposure assumptions to protect the health of subpopulations at potentially greater risk:

- Use of commonly consumed target species that are dominant in the catch and have the highest bioaccumulation potential

- Use of whole fish or whole body of shellfish (excluding shell of bivalves), which may provide a better estimate of contaminant exposures in subpopulations that consume whole fish or shellfish

- Use of the largest (oldest) individuals in the target species to represent the highest likely exposure levels

- Use of a 10^{-6} or 10^{-7} risk level, body weights less than 70 kg for women and children, site-specific consumption rates (i.e., 30 g/d for sport fisherman or 140 g/d for subsistence fishermen or other consumption rates based on dietary studies of local fish-consuming populations), and a 70-yr exposure period to calculate SVs for carcinogens. **Note:** The EPA is currently reviewing the consumption rate for sport and subsistence fishermen.

- Use of body weights less than 70 kg for women and children and site-specific consumption rates (i.e., 30 g/d for sport fishermen or 140 g/d for subsistence fishermen or other consumption rates based on dietary studies of local fish-consuming populations) to calculate SVs for noncarcinogens.

There are additional aspects of the screening study design that States should review because they affect the statistical analysis and interpretation of the data. These include

- Use of composite samples, which results in loss of information on the distribution of contaminant concentrations in the individual sampled fish and shellfish. Maximum contaminant concentrations in individual sampled fish, which can be used as an indicator of potentially harmful levels of contamination (U.S. EPA, 1989d), are not available when composite sampling is used.

- Use of a single sample per screening site for each target species, which precludes estimating the variability of the contamination level at that site and, consequently, of conducting valid statistical comparisons to the target analyte SVs.

- Uncertainty factors affecting the numerical calculation of quantitative health risk information (i.e., references doses and cancer slope factors) as well as human health SVs.

The use of composite samples is often the most cost-effective method for estimating average tissue concentrations of analytes in target species populations to assess chronic human health risks. However, there are some situations in which individual sampling can be more appropriate from both ecological and risk assessment perspectives. Individual sampling provides a direct measure of the range and variability of contaminant levels in target fish populations. Information on maximum contaminant concentrations in individual fish is useful in evaluating acute human health risks. Estimates of the variability of contaminant levels among individual fish can be used to ensure that studies meet desired statistical objectives. For example, the population variance of a contaminant can be used to estimate the sample size needed to detect statistically significant differences in contaminant screening values compared to the mean contaminant concentration. Finally, the analysis of individual samples may be desirable, or necessary, when the objective is to minimize the

impacts of sampling on certain vulnerable target populations, such as predators in headwater streams and aquatic turtles, and in cases where the cost of collecting enough individuals for a composite sample is excessive. For States that wish to consider use of individual sampling during either the screening or intensive studies, additional information on collecting and analyzing individual samples is provided in Appendix A.

States should consider the potential effects of these study design features when evaluating screening study results.

2.2 INTENSIVE STUDIES (TIER 2)

The primary aims of intensive studies are to assess the magnitude of tissue contamination at screening sites, to determine the size class or classes of fish within a target species whose contaminant concentrations exceed the SVs, and to assess the geographic extent of the contamination for the target species in the waterbody under investigation. With respect to the design of intensive studies, EPA recommends a sampling strategy that may not be feasible for some site-specific environments. Specifically, EPA recognizes that some waterbodies cannot sustain the same intensity of sampling (i.e., number of replicate composite samples per site and number of individuals per composite sample) that others (i.e., those used for commercial harvesting) can sustain. In such cases, State fisheries personnel may consider modifying the sampling strategy (e.g., analyzing individual fish) for intensive studies to protect the fishery resource. Although one strategy cannot cover all situations, these sampling guidelines are reasonable for the majority of environmental conditions, are scientifically defensible, and provide information that can be used to assess the risk to public health. Regardless of the final study design and protocol chosen for a fish contaminant monitoring program, State fisheries, environmental, and health personnel should always evaluate and document the procedures used to ensure that results obtained meet State objectives for protecting human health.

The allocation of limited funds to screening studies or to intensive studies should always be guided by the goal of conducting adequate sampling of State fish and shellfish resources to ensure the protection of the public's health. The amount of sampling that can be performed by a State will be determined by available economic resources. Ideally, State agencies will allocate funds for screening as many sites as is deemed necessary while reserving adequate resources to conduct subsequent intensive studies at sites where excessive fish tissue contamination is detected. State environmental and health personnel should use all information collected in both screening and intensive studies to (1) conduct a risk assessment to determine whether the issuance of an advisory is warranted, (2) use risk management to determine the nature and extent of the advisory, and then (3) effectively communicate this risk to the public. Additional information on risk assessment, risk management, and risk communication procedures will be provided in subsequent volumes in this series.